Mass General Brigham
Health Plan

Humira (adalimumab)
Effective 10/01/2020

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<tr><td>Plan</td><td>☐ MassHealth UPPL
☒Commercial/Exchange</td><td rowspan="2">Program Type</td><td rowspan="2">☒ Prior Authorization
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<tr><td>Benefit</td><td>☒ Pharmacy Benefit
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<tr><td rowspan="8">Contact Information</td><td colspan="3">Specialty Medications</td></tr>
<tr><td>All Plans</td><td>Phone: 866-814-5506</td><td>Fax: 866-249-6155</td></tr>
<tr><td colspan="3">Non-Specialty Medications</td></tr>
<tr><td>MassHealth</td><td>Phone: 877-433-7643</td><td>Fax: 866-255-7569</td></tr>
<tr><td>Commercial</td><td>Phone: 800-294-5979</td><td>Fax: 888-836-0730</td></tr>
<tr><td>Exchange</td><td>Phone: 855-582-2022</td><td>Fax: 855-245-2134</td></tr>
<tr><td colspan="3">Medical Specialty Medications (NLX)</td></tr>
<tr><td>All Plans</td><td>Phone: 844-345-2803</td><td>Fax: 844-851-0882</td></tr>
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Overview

Adalimumab is a recombinant monoclonal antibody that binds to human tumor necrosis factor alpha (TNF-alpha), thereby interfering with binding to TNFα receptor sites and subsequent cytokine-driven inflammatory processes.

Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Humira, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorizations may be granted for members who meet all diagnosis-specific criteria and documentation has been provided.

1. **Moderately to severely active rheumatoid arthritis (RA)**
   a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week) OR
   b. Member has an intolerance or contraindication to methotrexate (see Appendix A).
2. **Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)**
   a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate OR.
   b. Member has intolerance or contraindication to methotrexate (see Appendix A).
3. **Active psoriatic arthritis (PsA)**
   a. Member has had an intolerance to or inadequate response after at least 3 months of treatment with methotrexate OR leflunomide OR
   b. Member has a contraindication to BOTH methotrexate or leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

4. **Active ankylosing spondylitis (AS) and nonradiographic axial spondyloarthritis (nr-axSpA)**
    a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
    b. Member has an intolerance or contraindication to two or more NSAIDs.

5. **Moderately to severely active Crohn's disease (CD)**

Authorization may be granted for treatment of moderately to severely active CD if the member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix B).

6. **Moderately to severely active ulcerative colitis (UC)**

Authorization may be granted for treatment of moderately to severely active UC if the member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix C).

7. **Moderate to severe chronic plaque psoriasis (PsO)**

Authorization may be granted for treatment of moderate to severe plaque psoriasis when ALL the following criteria are met, and documentation is provided:

a. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
b. Member meets any of the following criteria:
c. Member has had an inadequate response or intolerance to TWO conventional therapies in any of the following combinations:
    i. 1 topical agent + 1 systemic agent (acitretin, cyclosporine, methotrexate)
    ii. 1 topical agent + 1 phototherapy
    iii. 1 systemic agent + 1 phototherapy
    iv. 2 systemic agents
d. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy, and systemic agents). See Appendix A
e. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

8. **Moderate to severe hidradenitis suppurativa**

Authorization may be granted for treatment of moderate to severe hidradenitis suppurativa (Hurley state II or III)

9. **Uveitis (non-infectious intermediate, posterior and panuveitis)**
    a. Member is at least 2 years of age AND
    b. Member has evidence of failure or inadequate response, contraindication, or documented intolerance to conventional therapy such as periocular, intraocular, or systemic corticosteroids OR immunosuppressive drugs (e.g., azathioprine, cyclosporine or methotrexate).

<u>Continuation of Therapy</u>

Reauthorizations for all diagnoses will be granted when documentation is submitted supporting improvement in member's condition.

Limitations

1. Approvals will be granted for 24 months
2. **For ALL indications,** member must have a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB). *
    a. Note: * Members who have received Humira or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.

Appendices

Appendix A: Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix B: Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
    a. Oral mesalamine
2. Mild to moderate disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternatives: methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission:
    a. Methotrexate IM
4. Moderate to severe disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – maintenance of remission
    a. Azathioprine, mercaptopurine
    b. Alternative: methotrexate IM

Appendix C: Examples of Conventional Therapy Options for UC

1. Mild to moderate disease – induction of remission:
    a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa)
    b. Rectal mesalamine (e.g., Canasa, Rowasa)
    c. Alternatives: azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
    a. Oral mesalamine, rectal mesalamine
    b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
    a. Sulfasalazine
4. Severe disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternative: sulfasalazine

5. Pouchitis: rectal mesalamine

Appendix D: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

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02/24/2014 – Reviewed and revised
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02/26/2018 – Reviewed and revised
11/26/2018 – Reviewed and revised (switched to Custom) in P&T Meeting
07/22/2020 – Reviewed and updated July P&T Mtg; reworded overview; changed diagnosis of axial spondyloarthritis to nonradiographic axial spondyloarthritis; updated references. Effective 10/01/2020.